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| 10/749,170 | 12/30/2003 | Daniel Gregorich | S63.2-11233US01 | 7868 |

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| EXAMINER | |
|---|---|
| TYSON, MELANIE RUANO | |

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| 3773 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/749,170 | GREGORICH, DANIEL | |
| | Examiner | Art Unit | |
| | Melanie Tyson | 3773 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *8 and 9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 10-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/12/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

This action is in response to Applicant's amendment received on 12 December 2007. Claims 8 and 9 remain withdrawn from consideration as being directed to a non-elected species.

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12 December 2007 has been entered.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-4 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant discloses embodiments having straight connecting elements and embodiments having curved connecting elements. However, the applicant failed to disclose an embodiment having a combination of straight connecting elements and curved connecting elements. Furthermore, the applicant discloses embodiments in which the curved elements are longer, thus include more peaks and troughs, but they are of the same shape. Therefore, the limitation "the

second connecting element *shaped differently* from the first connecting element" is considered indefinite. For examination purposes, the claims have been interpreted as including a second connecting element having a similar shape, but a different configuration than a first connecting element.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-4, 10, 13-17, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berra et al. (2004/0215319 A1) in view of Khosravi et al. (6,290,720 B1).

Berra discloses a stent (see entire document) comprising a plurality of closed circumferential serpentine bands formed of a single piece of material, where the strut length gradually increases and decreases around the circumference of each band (for example, see Figures 2A and 4). The struts of maximum length and minimum length

are generally longitudinally aligned (for example, see the Figures and paragraphs 41-47) and at least one serpentine band may have a different geometry from another serpentine band (for example, see Figure 2B). Berra fails to disclose a first connecting element and a second connecting element, wherein the second connecting element is shaped differently from the first connecting element.

Khosravi discloses a device (see entire document) comprising a plurality of closed circumferential serpentine bands formed of a single piece of material (for example, see Figure 2). Khosravi teaches it is well known in the art to utilize connecting elements (34) to connect the serpentine bands to one another. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Berra as taught by Khosravi. Doing so would provide a connection between the serpentine bands (for example, see column 4, lines 62-66), thus providing alignment between bands. With further respect to claims 13, connecting elements between the struts of minimum length would have a greater length than connecting elements between the struts of maximum length in Berra's device. With further respect to claim 22, Khosravi discloses the bands do not have to be individually attached to the graft wall, thus the stent may not be *part of* the stent-graft.

Berra in view of Khosravi discloses the claimed invention except for connecting struts shaped differently. It would have been an obvious matter of design choice to provide a second connecting element shaped differently from a first connecting element, since the applicant has not disclosed that connecting elements of different shapes

solves any stated problem or is used for any particular purpose and it appears that the invention would perform equally well with connecting elements having the same shape.

With further respect to claim 14, Berra in view of Khosravi discloses the claimed invention except for connecting elements being nonparallel to a central longitudinal axis of the stent. It would have been an obvious matter of design choice to provide the connecting elements nonparallel to a central longitudinal axis of the stent, since the applicant has not disclosed that connecting elements being nonparallel to a central longitudinal axis solves any stated problem or is used for any particular purpose and it appears that the invention would perform equally well with connecting elements that are parallel to the longitudinal axis.

With further respect to claim 16, Berra in view of Khosravi discloses the claimed invention except for maximum length struts of one band being shorter than the maximum length struts of a second band. It would have been an obvious matter of design choice to modify the distribution of struts between bands such that maximum length struts of one band are shorter than the maximum length struts of a second band, since the applicant has not disclosed that this particular distribution solves any stated problem or is used for any particular purpose and it appears that the invention would perform equally well with bands having maximum length struts of the same length.

7. Claims 5-7, 11, 12, 18, 19, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berra et al. in view of Khosravi et al. and Yip et al. (2004/0230293 A1).

Berra discloses a stent (see entire document) comprising a plurality of

closed circumferential serpentine bands formed of a single piece of material, where the strut length gradually increases and decreases around the circumference of each band (for example, see Figures 2A and 4). The struts of maximum length and minimum length are generally longitudinally aligned (for example, see the Figures and paragraphs 41-47) and the turns of the bands are non-aligned. Berra fails to disclose connecting elements and that the turns of the serpentine bands are in general circumferential alignment at only one end of the band.

Khosravi discloses a device (see entire document) comprising a plurality of closed circumferential serpentine bands formed of a single piece of material (for example, see Figure 2). Khosravi teaches it is well known in the art to utilize connecting elements (34) to connect the serpentine bands to one another. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Berra as taught by Khosravi. Doing so would provide a connection between the serpentine bands (for example, see column 4, lines 62-66), thus providing alignment between bands. With further respect to claim 18, connecting elements between the struts of minimum length would have a greater length than connecting elements between the struts of maximum length in Berra's device.

Yip discloses an intravascular stent comprising struts and connecting elements (see entire document). Yip teaches bands, wherein the turns are in general circumferential alignment at only one end of the band (for example, see Figure 37). It is well known in the art that varying the position of struts has an affect on the flexibility of stents. It is also well within the general knowledge of one having ordinary skill in the art

to choose from a finite number of identified, predictable solutions with a reasonable expectation of success. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to try aligning the turns at only one end of the band, as recited in claims 5-7, as taught Yip. Doing so would vary the flexibility of the device, thus providing a device that has sufficient flexibility for its intended use (i.e., either for a more or less tortuous vessel). With further respect to claims 11, 12, 18, and 21, Yip further teaches connecting elements having a peak and a valley (for example, see Figure 39). It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize connecting elements having a peak and a valley in Berra's device as taught by Yip. Doing so would allow the connecting elements to easily expand radially outwardly or compress radially inwardly, thus facilitating deployment and emplacement of the device (for example, see paragraph 81).

8. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berra et al. in view of Khosravi et al. and Yip et al. as applied to claim 18 above, and further in view of Oepen et al. (2002/0161428 A1).

Berra in view of Khosravi and Yip fails to disclose struts of varying thickness. Oepen discloses a stent (see entire document). Oepen teaches that the thickness of connecting elements and struts may be varied to tailor stents to specific applications. It is well within the general knowledge of one having ordinary skill to use a known technique to improve similar devices in the same way. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify

the thickness of the struts of Berra in view of Khosravi and Yip as taught by Oepen such that some struts are thinner than others. Doing so would provide the stent with greater flexibility where desired to accommodate certain vessels or arteries that would require such characteristics along the stent (for example, see paragraph 15).

***Response to Arguments***

9. Applicant's arguments with respect to claims 5, 13, and 16 have been considered but are moot in view of the new ground(s) of rejection.

10. Applicant's arguments filed 12 December 2007 have been fully considered but they are not persuasive. Applicant argues primarily that the combination of the prior art applied to the claims is improper. Examiner respectfully disagrees.

Applicant argues that adding Khosravi connectors to the Berra device is unnecessary since the graft material provides alignment between the Berra bands and adding connectors would decrease the flexibility of the Berra device making it inoperable in a tortuous anatomy. However, Khosravi teaches that the bands may be individually attached to the peripheral wall **and/or** the bands may be connected to one another by one or more connector elements extending between adjacent bands (for example, see column 2, lines 11-20). Therefore, utilizing connector elements Berra's device would ensure proper connection and alignment between the bands. Furthermore, Khosravi teaches the device is sufficiently flexible to accommodate a tortuous anatomy. Therefore, in contrast to the applicant's arguments, Berra's device would still have sufficient flexibility to traverse a tortuous anatomy and properly deploy on a curve if connecting elements were added.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 8:30-7.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./
Examiner, Art Unit 3773
February 28, 2008

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773